



## NEW ZEALAND EMBASSY

TE AKA AORERE  
WASHINGTON

0003 '03 APR -4 P12:18

3 April 2003

Ms Leslye M Fraser  
Associate Director for Regulations  
Mail Code HFS-4  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
5100 Paint Brush Parkway  
College Park, MD 20740

Dear Ms Fraser

I refer to the Federal Register Notice inviting comments on the rules proposed by the Department of Health and Human Services' Food and Drug Administration (FDA) under the *Public Health Security and Bioterrorism Preparedness and Response Act 2002 (Bioterrorism Act)* - Docket No. 02N-0278 and Docket No. 02N-0276.

The New Zealand Government welcomes the opportunity to provide comments on the proposed rule made under the Bioterrorism Act. New Zealand shares the US' concerns related to bioterrorism and supports the intention of the Bioterrorism Act to provide appropriate prevention measures against potential bioterrorism. However some aspects of the way in which the US plans to implement measures to address these concerns appear likely to add unnecessary costs or raise other difficulties for New Zealand exporters. We therefore wish to work with the US to identify ways in which the basic US concerns can be addressed in ways that minimise costs to New Zealand. New Zealand's main concerns are listed below.

- Recognition of New Zealand's measures for food products as equivalent as provided for under the WTO Agreement on Sanitary and Phytosanitary Measures;
- Time zone issues that arise for New Zealand as result of exporting to the US across the international date-line;
- Discrepancies in US definition of port of entry;
- Confidentiality and commercial sensitivity issues arising with the use of a single US agent;

**02N-0278**

**C199**

More generally, New Zealand notes that parts of the proposed rule(s) duplicate and conflict with rules under US Customs jurisdiction. New Zealand would appreciate urgent advice of how these two sets of rules are to be harmonised and under what timeframes.

In addition, the proposed rules require prior notification and establishment registration of food facilities without documenting the level of protection sought by FDA or providing a risk assessment.

New Zealand understands that FDA also intends to substantively increase port inspection staff and laboratory capability. New Zealand would appreciate further written clarification on these matters, for example when a risk assessment will be done, when will the US establish its ALOP and information about proposed increases in inspection staff and when this is likely to occur and when expanded laboratory capability is expected to occur.

New Zealand's specific comments on the two dockets are contained below.

New Zealand appreciates its close working relationship with the US, including on SPS issues, and we look forward to continuing this cooperation. New Zealand hopes to work together with the US to develop measures which meets the concerns which the Bioterrorism Act is intended to address whilst doing so in a manner that minimises costs and other negative trade effects and is the least trade-restrictive as possible.

I would welcome the opportunity to discuss New Zealand's concerns with you further.

With kind regards

Yours sincerely

A handwritten signature in black ink that reads "John Wood". The signature is written in a cursive, flowing style.

John Wood  
**Ambassador**

**PRIOR NOTICE OF IMPORTED FOOD****General comments**

Section 307 of the proposed rule requires prior notification of food shipments to FDA. The notice must include a description of the article, the manufacturer and shipper, the grower (if known), the country of origin, the country from which the article is shipped, and the anticipated port of entry.

One aspect of concern to New Zealand is the fact there is a duplication of information required by FDA and that required by US Customs Services' Container Security Initiative. Additionally there are areas where one agency has a requirement and the other has variations on that requirement such as for port of entry. These security programmes affect business and trade in similar ways. New Zealand would encourage the FDA and US Customs to urgently co-ordinate their efforts and remove the costly and onerous areas of duplication in their requirements of imported food products.

**Port of entry**

FDA defines the port of entry as the first US port of call, whereas US Customs may allow a shipment to be moved under bond from the first port of call to another where it is processed for entry. New Zealand should be grateful if the US authorities would harmonise these definitions as quickly as possible.

**Airfreight/ Dateline issues for prior notification**

The proposed rule, in Section 1.286, requires prior notice of shipment to be lodged with FDA between 5 days through to noon of the calendar day prior to the intended day of arrival in the US. New Zealand air cargo consignments will in reality be arriving, particularly on the western seaboard, on a date and time before they have departed from New Zealand. The timing in the example below means that a prior notice needs to be lodged in anticipation of a consignment being able to be sent and potentially adds costs because of the need to make last minute amendments to the original information provided.

An example for a consignment shipped from Auckland New Zealand to Los Angeles (LA) is outlined below:

A last minute decision to load a consignment is made on a flight departing Auckland at 4.00 pm on the 16<sup>th</sup> of the month. This time is equivalent to 12 noon LA time on the 15<sup>th</sup>. Allowing for a 13 hour flight time the consignment arrival would be as follows:

New Zealand time when consignment arrives in LA is 5.00 am on the 17<sup>th</sup>. Arrival time in LA is 1.00 p.m. on the 16<sup>th</sup>.

Air cargo has an element of uncertainty with regard to obtaining available space. Last minute decisions as to whether a particular consignment will be loaded are not uncommon. This fact compounds the timing issue identified above. Additionally, it will commonly lead to many prior notifications having to be modified. It will also give rise to periodic "no shows" of consignments that have been notified to FDA to meet the noon deadline, on the basis that it may be shipped.

New Zealand would like an assurance that exporters will not be subject to any penalty actions due to such situations that are beyond their control.

As a result of the uncertainties described above there will be heavy dependence upon airlines advising New Zealand exporters of the details of consignment actually loaded in a timely fashion. Again an added cost to exporters.

#### **Sea cargo prior notification issues**

It is not uncommon practice for importers to only become aware of consignments once they have arrived and possibly been devanned. The timing of the prior notification under the proposed rule requires a significant change in this practice and potentially could lead to significant problems during the initial implementation of this rule at least. It is assumed that shipping companies would be the main vehicle for advising importers of expected arrival dates. Any breakdown in this communication would put the importer in default, cause delays to consignments being cleared, and contribute to increased costs for New Zealand exporters for matters that are out of their control.

New Zealand proposes that FDA give consideration to providing greater flexibility by allowing prior notification to be submitted at or around the time of loading a vessel. If the prior notification system had a flagging mechanism tied to the expected date of arrival as a bring up mechanism, FDA would still be able to access the information within the time frames currently proposed.

New Zealand also requests that both FDA and US Customs give high priority to harmonising their electronic system to facilitate the prior notification process thereby minimising costs for our exporters.

#### **Prior notification submission**

The proposed rule, under Section 1.285, requires a person resident in the US to carry out this function. For New Zealand exporters, it is likely that one contact person will be nominated for both FDA and US Customs Service programmes and will essentially supply duplicate information in order to satisfy both FDA and US Customs requirements. New Zealand is concerned that this situation is unnecessary and simply imposes additional costs on our exporters.

New Zealand also requests that both FDA and US Customs give high priority to harmonising their electronic system to facilitate the prior notification process thereby minimising costs for our exporters.

In addition, we suggest that FDA objectives would, at least, be equally served if New Zealand food exporters or their agents in New Zealand were permitted to submit prior notification. New Zealand request that FDA consider this option, not just in terms of eliminating confidentiality and other commercial-related issues for New Zealand exporters, but also in terms of the advantages for FDA to go direct to source if an issue does arise that requires contact with exporters or their agents

### **Certification**

New Zealand is concerned at the amount of information that has to be submitted by prior notification and the lack of recognition for equivalent means of providing this information.

The proposed rule does not take into consideration the fact that government to government certification for consignments of many food commodities from New Zealand already provides most of the information required by FDA. It particularly ignores the fact that New Zealand has electronic certification, especially in the form of E-cert as developed by the New Zealand Food Safety Authority. Information would be supplied to FDA, which would allow FDA to view details of a consignment prior to arrival in a secure format. E-cert currently has the capability that would allow FDA to facilitate identification and prioritisation of activities when selecting consignments of New Zealand food products for inspection at the border.

For those commodities and the information required by FDA which is not already covered by NZFSA' E-cert, New Zealand proposes that negotiations take place to achieve resolution.

New Zealand requests that FDA consider the use of electronic certification as a vehicle for secure prior notification, thereby eliminating duplication of information for New Zealand exporters.

## **REGISTRATION OF FOOD FACILITIES**

Section 305 of the proposed rule requires all foreign food facilities that manufacture, process, pack or hold food for human or animal consumption to register the facility with FDA before 12 December 2003.

### **Information required for registration**

There is considerable duplication of the information required by US Customs and that required by FDA. It is apparent that no immediate measures are being put into place to address this issue and thereby facilitate the introduction of these proposals in a more efficient manner.

As with meat establishments exporting to the USA New Zealand also manages listing (registration) of dairy and seafood premises with regard to their eligibility to process for and export to the USA. For seafood premises there is notification to FDA of premises under the ICSS Certification process and provision of a premises list for seafood premises that comply with HACCP requirements. Therefore, providing additional registration information at least in part is duplicating these lists.

In the horticultural field for Kiwifruit the individual facility will register directly with FDA and FDA will allocate a registration number, however, the packaging on the consignments sent to the US will only identify the a single exporting organisation and it's address. This is because they export into the US market on behalf of New Zealand producers. There is nothing on the packaging that will identify the last facility to handle the food product prior to export to the US. Therefore, if there should be a problem how will the appropriate people be contacted? It would appear that there is a presumption that the facility will have its details on the packaging when that is not the case.

### **US agent to be identified**

New Zealand industry has concerns with regard to this aspect. The most likely agent to be used by a New Zealand exporter would be an importer/customs broker. However, some New Zealand exporters would use more than one agent to handle their consignments depending upon the port of entry into the US. Their concerns relate to issues of confidentiality and commercial sensitivity when the chosen agent is dealing with business information pertaining to another US-based agent (potentially a commercial company) not covered by the registration.

New Zealand requests that the nomination of more than one US agent, at the time the New Zealand exporter registers with FDA, be permitted to overcome these issues. The relevant agent for each consignment could be included in the prior notification. Alternatively, the competent authority could be a contact point.

**Chartered fishing vessels**

Chartered fishing vessels operate for parts of the year within the New Zealand EEZ and consequently could be registered under different US agents for different companies. This could result in confusion with the added issue of different origins depending upon whether the vessel is operating under its New Zealand charterer within our EEZ, or operating elsewhere.

**New Zealand vessels operating in more than one jurisdiction**

Some New Zealand vessels operate in other jurisdictions and often change registry too. As such the same concerns as those for charter vessels arises. Product from the same vessel will have different origins